UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. **Plaintiff,** **v.** **FOOD AND DRUG ADMINISTRATION,** **et al.,** **Defendants,** **APOTEX INC.,** **Intervenor-Defendant.**	**Civil Action No. 05-1469 (JDB)**

MEMORANDUM OPINION

Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva"), has sued defendant Food and Drug Administration ("FDA"), and defendants Michael O. Leavitt and Lester M. Crawford in their official capacities as the Secretary of Health and Human Services and the Commissioner of Food and Drugs, respectively. This action is the latest step in an ongoing dispute relating to whether dismissals of patent infringement declaratory judgment actions are recognized as court "decisions" under the law addressing abbreviated new drug applications. Teva challenges FDA's

actions under: (1) the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), codified at 21 U.S.C. § 355; and (2) the Administrative Procedure Act, 5 U.S.C. § 706(2). Teva seeks declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the issuance of injunctive relief. For the reasons discussed below, the Court finds that FDA's actions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law" under § 706(2) and that Teva is therefore entitled to the relief sought.

BACKGROUND

Teva is a pharmaceutical company, incorporated in Delaware and headquartered in Pennsylvania, that "develop[s], manufacture[s], and market[s]" generic versions of already-approved (or "branded") pharmaceuticals in the United States. Compl. at 3-4 ¶ 7. On December 20, 2000, Teva filed an abbreviated new drug application ("ANDA") with FDA, seeking permission to market the generic equivalent of the drug pravastatin sodium ("pravastatin") in 10 mg, 20 mg, and 40 mg doses. See Administrative Record ("Admin. Rec.") Exhs. 1, 2. Bristol-Myers Squibb Company ("BMS") holds four patents associated with Pravachol®, the branded version of pravastatin. See Admin. Rec. Exh. 2; see also Admin. Rec. Exhs. 3, 4. Pravachol® is a drug that is prescribed to treat high cholesterol and cardiovascular disease. See Admin. Rec. Exh. 2. The BMS patents are on file with FDA as numbers 4,346,227 ("'227 patent"); 5,030,447 ("'447 patent"); 5,180,589 ("'589 patent"); and 5,622,985 ("'985 patent"). See Admin. Rec. Exh. 8 at 1. The '227 patent, expiring on April 20, 2006, claims the pravastatin compound itself, see Pl.'s Mem. in Support of Appl. for Prelim. Inj. at 7-8 ("Pl.'s Mem. in Supp."); the '447 and '589

patents claim specific formulations of the drug, see Pl.'s Mem. in Supp. at 7-8; and the '985 patent claims a particular method of use, see Admin. Rec. Exh. 7 at 5.

As required by the Hatch-Waxman Act, Teva filed certifications for each of the four BMS patents when it filed its ANDA. See Admin. Rec. Exhs. 7, 8 at 1-2; see also Admin. Rec. Exh. 3. Teva filed a paragraph III certification with respect to the '227 patent, stating that it did not intend to challenge the compound patent or to market generic pravastatin before the patent expires in April 2006. See Admin. Rec. Exh. 8 at 1-2; see also Admin. Rec. Exh. 3. For each of the remaining three patents, Teva filed a paragraph IV certification, asserting that the generic product would not infringe any of those patents and/or that those patents were invalid. See Admin. Rec. Exh. 8 at 1-2; see also Admin. Rec. Exh. 3. Following Teva's filing, at least seven competing generic pharmaceutical companies, including intervenor Apotex Inc. ("Apotex"), filed similar applications that also consisted of paragraph III certifications for the '227 patent and paragraph IV certifications for the remaining three patents. See BMS's Mem. of Law in Support of Def.'s Mot. to Dismiss Pl.'s Compl. in Apotex Inc. v. Bristol-Myers Squibb Co., No. 1:04-CV-2922 (S.D.N.Y.) at 7 ("BMS-Apotex Litig. Mem. Supp."). The filing of a paragraph IV certification is itself considered an act of infringement, entitling -- but not requiring -- the patent holder to bring suit against the filer, or any subsequent filer, immediately. See 35 U.S.C. § 271(e); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). BMS did not sue Teva or any of the subsequent filers. See BMS-Apotex Litig. Mem. Supp. at 9; see also Admin. Rec. Exh. 5 at 1.

As the first to file a paragraph IV certification, Teva was entitled to a 180-day period of marketing exclusivity, during which no other entity may market generic pravastatin. See 21

U.S.C. § 355(j)(5)(B)(iv)(II). This 180-day clock begins to run from the earlier of either the date on which the first filer commercially markets the generic drug, or the "date of a decision of a court in an action . . . holding the patent which is the subject of the certification to be invalid or not infringed." Id. Teva estimates that this 180-day exclusivity period will push its total sales receipts two to three times higher during the first year that it markets generic pravastatin, with net revenues reaching hundreds of millions of dollars. Pl.'s Mem. in Supp. at 30. FDA tentatively approved Teva's application on May 20, 2002. Admin. Rec. Exh. 8. Teva never began marketing generic pravastatin. See Admin. Rec. Exh. 11.

On October 27, 2003, Apotex, one of the subsequent filers, sent a letter to BMS, in which it asked BMS to "agree in writing that Apotex's proposed generic pravastatin sodium product 'does not and will not infringe the '447, '589, and '985 patents.'" See BMS-Apotex Litig. Mem. Supp. at 8. Although BMS never made such a guarantee of non-infringement, it did state in three separate letters, dated November 10, 2003, February 13, 2004 and February 20, 2004, that it did not intend to sue Apotex for infringement. See BMS-Apotex Litig. Mem. Supp. at 2. For example, the February 20, 2004 letter stated that BMS "has no intention, now or in the future, of suing [Apotex] for infringement of any of the three BMS patents so long as [Apotex's] previous representations about its proposed generic products remain accurate." Id. Apotex nonetheless filed suit against BMS on April 15, 2004 in the United States District Court for the Southern District of New York, pursuing a declaration of non-infringement, invalidity, and/or unenforceability. See Compl. in Apotex Inc. v. Bristol-Myers Squibb Co., No. 1:04-CV-2922, at 34 (S.D.N.Y.) (filed Apr. 15, 2004) ("BMS-Apotex Litig. Compl.").

BMS moved to dismiss on the grounds that no case or controversy existed because BMS had repeatedly assured Apotex that it had no intention of suing for infringement; therefore, Apotex could not reasonably fear suit by BMS. See BMS-Apotex Litig. Mem. Supp. at 2, 8, 12-13. Rather than litigating the motion, Apotex then withdrew its lawsuit by procuring a joint stipulation of dismissal, which stated that the action was to be dismissed for lack of subject matter jurisdiction. See Stipulation and Order in Apotex Inc. v. Bristol-Myers Squibb Co., No. 1:04-cv-2922, at 34 (S.D.N.Y.) at 3 ("BMS-Apotex Litig. Stip."). This document was a voluntary, consensual stipulation that was agreed to by Apotex and BMS without court involvement, signed by both Apotex and BMS without court involvement, and then submitted to the district court for its signature. The stipulation was procured before any arguments or hearings had taken place; in fact, BMS had not yet filed an answer to the complaint. Motions Hearing Tr. at 8 ("Tr."). In every way, the stipulation was wholly uncontested.

On July 23, 2004, the district court entered the stipulated dismissal order as submitted by the parties. Id. The dismissal order did not mention whether the dismissal was made with prejudice, see id., but it expressly based the dismissal on the fact that

> prior to Apotex's filing of the Complaint herein, BMS repeatedly represented and assured Apotex that, notwithstanding any disagreement on the scope or interpretation of the claims of the '447, '985, and '589 patents, it had no intention to bring suit against Apotex for infringement of the '447, '985, and '589 patents with respect to Apotex's generic pravastatin sodium products that are the subject of ANDA No. 76-341.

BMS-Apotex Litig. Stip. at 3.

Nearly a year later, on June 28, 2005, FDA informed Teva by letter that Teva's 180-day exclusivity clock had been triggered by the dismissal of the BMS-Apotex lawsuit. See Admin.

Rec. Exh. 11 at 1. Accordingly, FDA deemed the exclusivity period to have expired on February 18, 2005. Id. FDA considered the BMS-Apotex dismissal to be a "decision of a court with respect to any ANDA, in which the court holds the relevant patent is invalid, unenforceable or not infringed" under 21 U.S.C. § 355(j)(5)(B)(iv)(II). See id. at 4-5. This finding was based on FDA's interpretation of two prior cases decided by the D.C. Circuit: Teva Pharms. USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999) ("Teva I"), and Teva Pharms. USA, Inc. v. FDA, 2000 WL 1838303 (D.C. Cir. 2000) (unpublished disposition) ("Teva II"). Id. at 3. FDA has interpreted these cases to establish that a "dismissal of a declaratory judgment action may qualify as a 'decision of a court' triggering the running of the 180-day exclusivity period if the dismissal estops a future action against the ANDA holder for infringement of the patent with respect to that drug product." Id. Because the BMS-Apotex dismissal was based upon representations by BMS that it had no intention to sue Apotex for infringement of the three patents, FDA viewed the representations as preclusive of a future infringement suit by BMS against Apotex. Id. at 3-4.

Teva filed a complaint for declaratory relief in this Court on July 26, 2005, asserting that FDA's action was arbitrary, capricious, and constituted an abuse of discretion under APA § 706(2), and seeking preliminary and permanent injunctive relief to enjoin FDA from approving the ANDAs of competing generic pharmaceutical companies. On August 1, 2005, Apotex was added as an intervenor-defendant by stipulation of the parties. At the request of the parties, this Court has consolidated the motion for injunctive relief with a hearing on the merits pursuant to Fed. R. Civ. P. 65(a)(2). See Order of Aug. 8, 2005 at 2.[1]

[1]This type of consolidation is a procedural tool designed to conserve the resources of the Court and the parties by avoiding duplicative efforts. See NOW v. Operation Rescue, 747 F. Supp. 760, 768 (D.D.C.

ANALYSIS

The heart of the parties' disagreement centers on the scope and application of the Teva I and Teva II decisions. Teva's position is that Teva I establishes a two-part test: (1) there must be a "decision of a court" or "holding" within the meaning of the Hatch-Waxman statute; and (2) that "decision" or "holding" must have preclusive effect. Teva Suppl. Brief at 2, 3-9 ("Pl.'s Suppl. Br."); Tr. at 6-9, 10. The crux of Teva's argument is that the first prong of this test is not met here, but that even if the first prong is met, FDA cannot satisfy the second prong. Pl.'s Suppl. Br. at 2; Tr. at 9, 13. With respect to Teva II, Teva submits that the decision is not binding precedent because it is an unpublished opinion, and the Court should instead look to the well-established precedent of Dart Drug Corp. v. Schering Corp., 320 F.2d 745, 749 (D.C. Cir. 1963). See Pl.'s Mem. Supp. at 19; Tr. at 14.

Teva submits that the district court's signature on the BMS-Apotex dismissal was not required because the stipulation was a "private agreement" between the parties, to be read within its four corners only -- i.e., it required no judicial action whatsoever. Tr. at 9, 14; Pl.'s Suppl. Br. at 4-8. Apotex, the plaintiff in the BMS-Apotex litigation, dismissed its own lawsuit with the defendant's consent, on terms decided between the parties and based upon the defendant's pre-suit representations. See Pl.'s Suppl. Br. at 6-7; see also Tr. at 6-7. The district court weighed no evidence and made no judgments. Thus, Teva maintains, the mere presence of the district court's signature on the order and an awareness of the representations made by BMS does not constitute "judicial imprimatur." Pl.'s Suppl. Br. at 7 (citing Kokkonen v. Guardian Life Ins. Co. of Am.,

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1990). Such proceedings are akin, but not identical in the administrative law context, to summary judgment.

511 U.S. 375, 381 (1994)). According to Teva, this Court is limited to what the district court considered when it entered the dismissal -- the Court may not look beyond the stipulation to what the parties had relied upon. Pl.'s Suppl. Br. at 3-4; Tr. at 7, 11-12.

As a fallback argument, Teva submits that even if the BMS-Apotex dismissal does qualify as a "decision" or "holding," Teva I and Teva II still do not support FDA's actions in this case. See Teva's Reply Mem. in Support of Appl. for Inj. and Decl. Relief at 2-3 ("Pl.'s Reply Mem."). Specifically, Teva interprets those cases to establish that the dismissal of a declaratory judgment action can trigger the 180-day exclusivity clock as long as that dismissal has preclusive effect -- that is, as long as it estops a future lawsuit based on patent infringement, invalidity, or unenforceability. See id. The BMS-Apotex dismissal, Teva argues, lacks preclusive effect because BMS never promised not to sue in the future: BMS only made representations about its present lack of intent to sue. Pl.'s Mem. in Supp. at 4, 24-28. Significantly, BMS never conceded that its patents were unenforceable or that they would not be infringed by Apotex's actions, id. at 3-4, and the dismissal does not purport to have been made "with prejudice," id. at 11, 28. Because the dismissal was predicated on a lack of subject matter jurisdiction, Teva submits that the district court could not have actually "held" anything, and therefore FDA's determination that this dismissal was a court decision "holding" a patent invalid or not infringed within the meaning of the Hatch-Waxman Act is substantively incorrect. See Pl.'s Mem. in Supp. at 22-23.

As a threshold matter, FDA believes that Teva is drawing a very fine and irrelevant distinction that is not supported by the existing case law. See FDA's Supplemental Brief at 3-5 ("Def.'s Suppl. Br."); Tr. at 34. In any event, FDA considers the BMS-Apotex dismissal to

constitute a "decision" and "holding." Def.'s Suppl. Br. at 4; Tr. at 34. FDA claims that whether the district court's signature was required is unimportant because, in the situation at hand, its signature is actually on the face of the order. Def.'s Suppl. Br. at 4-5; Tr. at 46. This signature functions to "transform[] it from a stipulation or a proposed order into an actual order of the court." Id. at 5. Because "a federal court always has jurisdiction to determine its own jurisdiction," United States v. Ruiz, 536 U.S. 622, 628 (2002) (citing United States v. United Mine Workers of Am., 330 U.S. 258, 291 (1957)), the district court's finding that it lacked subject matter jurisdiction cannot be rendered a nullity simply because it was made subsequent to the parties' private agreement on that point. Def.'s Suppl. Br. at 6. Thus, FDA submits, the district court was not divested of jurisdiction at the moment that the BMS-Apotex dismissal was signed by the parties, and its signature still had the power to render a "holding." Just as parties cannot stipulate to the existence of jurisdiction, they cannot stipulate to the absence of it.[2] Def.'s Suppl. Br. at 6; Tr. at 78.

FDA interprets Teva I and Teva II as follows,[3] see FDA's Mem. in Opp'n at 27, 28-29

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[2]It is undoubtedly true that parties cannot stipulate to the existence of jurisdiction. However, they can agree to the absence of a case or controversy, as happened between Apotex and BMS. The lack of a case or controversy functions to revoke subject matter jurisdiction. Thus, it is not *exactly* true that parties cannot stipulate to the lack of jurisdiction. But cf. Mondy v. Sec'y of the Army, 845 F.2d 1051, 1055 (D.C. Cir. 1988) (stating that a court must determine its own jurisdiction, irrespective of the opinions of the litigants). It is also true that, as this opinion discusses, under Federal Rule of Civil Procedure 41(a)(1)(ii), a case can be voluntarily dismissed without any court action, upon agreement of the parties and the filing of a signed stipulation.

[3]Initially, FDA urged this Court to give deference to its view of the meaning of Teva I and Teva II, and the "decision of a court" trigger of the Hatch-Waxman Act, based on Chevron U.S.A. v. Natural Res. Defense Council, 467 U.S. 837 (1984). See Def.'s Mem. Opp'n at 19-21. As FDA itself acknowledged, id. at 19, Chevron applies to matters of statutory interpretation. It is not implicated in this case, which focuses on FDA's interpretations of judicial precedent. Because counsel for FDA unequivocally withdrew the Chevron deference argument at the motions hearing, the Court need not address it further.

("Def.'s Mem. Opp'n"): (1) Teva I establishes that the dismissal of a declaratory judgment action is sufficient to trigger the 180-day exclusivity clock if that dismissal has preclusive effect, see id. at 22-23; and (2) Teva II establishes that the FDA may "look beyond the face of the court order if necessary to determine whether the dismissal of the declaratory judgment action had [such] preclusive effect," see id. at 23. Under Teva I, then, FDA submits that the essential inquiry centers on the preclusive nature of BMS's statements. See Def.'s Suppl. Br. at 9 (citing Teva I). And under Teva II, FDA was required to look beyond the BMS-Apotex stipulation at the underlying representations and correspondence, because Teva II makes clear that the stipulation is not to be limited to its four corners. Tr. at 53.

FDA maintains that the representations by BMS to Apotex in the BMS-Apotex case -- including the "assurance[s] that it did not intend to sue Apotex, 'now or in the future,'" Def.'s Mem. Opp'n at 25, and the statement that this intention would not change unless Apotex's representations about its generic product ceased to remain accurate -- function to estop BMS from bringing a future lawsuit against Apotex. See Def.'s Mem. Opp'n at 25, 35 n.16. FDA views the facts of this case as indistinguishable from the facts of the previous Teva litigation, and reads neither those cases nor the applicable Federal Circuit case law regarding patent estoppel to require express concessions of non-infringement. See id. at 30-31. To the contrary, a "mere disavowal of any intent to sue" is all that is necessary. Id. FDA asserts that the assurances by BMS were promises not to sue in the future, see id. at 33-35 & n.16, and the BMS-Apotex dismissal was expressly based upon those assurances; hence, the assurances are now enforceable

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See Tr. at 28-29.

under the law, and therefore preclude future suit, see id. at 38. For FDA, all of this compels the conclusion that Teva's 180-day exclusivity period was triggered by the BMS-Apotex dismissal, and Teva's exclusivity period is now exhausted -- indeed, it was exhausted even before FDA informed Teva of its determination.

The parties' arguments make clear that the outcome of this case turns on the intricacies of interpreting and applying Teva I and Teva II. Those decisions have apparently left FDA without a practical framework for adjudication, and FDA is searching for clear lines to use in making determinations under the Hatch-Waxman "court decision" statutory trigger. The Court is sympathetic to FDA's predicament. Nonetheless, the Court must decide this case based on the FDA's action, the relevant statutory language, and governing authority (including Teva I and Teva II). Before the Court can analyze whether FDA's action in the instant case was warranted, the prior Teva decisions must first be examined closely.

1. The Prior Teva Litigation

The starting point for this assessment is Teva I. There, Teva was a subsequent ANDA applicant seeking to market ticlopidine, the generic version of the branded drug Ticlid®, which is used to treat stroke victims. Teva I, 182 F.3d at 1006. Teva sought to accelerate the 180-day exclusivity period of TorPharm (now Apotex), the first ANDA applicant, by filing a declaratory judgment suit against the patent holder (Syntex) in the Central District of California.[4] Id. On the

[4]The briefs filed by Apotex and FDA assert that Teva is estopped from arguing its position in this case because that position is the opposite of what Teva argued in Teva I and Teva II. See Apotex Mem. Opp'n at 30; FDA Mem. Opp'n at 28-29, 36-37. FDA has since retreated from this argument, see Tr. at 26, but Apotex has not, see Apotex Suppl. Br. at 2, 9. As the Court made clear at the motions hearing, all the parties in this case have, at various times, taken legal positions in earlier cases that are inconsistent with the ones they advance here. Those shifts have occurred as the courts and FDA have made decisions, which have then been applied. But no party has been inconsistent in *this* case. The Court will therefore

same day that Teva filed suit, and before Syntex was served, Syntex sent a letter that expressly conceded that Teva's proposed ticlopidine product would not infringe its patent. Id.; Transcript from Teva Pharms. USA, Inc. v. Syntex USA, Inc., Civil No. 98-02314 (C.D. Cal. Aug. 14, 1998) at 21 ("Dist. Ct. Tr. from Teva-Syntex Litig."). The language of that letter, dated June 8, 1998, was as follows:

> Based on the information that [Teva] provided us, we are of the opinion that the formulation used in [Teva's] ticlopidine hydrochloride tablets does not infringe U.S. Patent 4,591,592. We will make no claim of patent infringement based on the sale of ticlopidine hydrochloride tablets having the formulation that [Teva] disclosed to us.

Mem. of Points and Authorities in Support of Teva's Mot. for a Prelim. Inj. in Teva I at 3 ("Pl.'s Teva I Mem. in Supp.").

Based on this admission, the parties agreed that there was, at that time, no case or controversy because Teva could not have a reasonable apprehension that Syntex would sue for infringement. See Pl.'s Teva I Mem. in Supp. at 4. The residual disagreement centered on what the dismissal should say and how it should be styled. Dist. Ct. Tr. from Teva-Syntex Litig. at 3, 6-7. Teva wanted a consent judgment that incorporated the effect of the June 8, 1998 letter, stating that "the manufacture, use or sale of the ticlopidine hydrochloride tablets for which Teva USA submitted an [ANDA] to the U.S. Food and Drug Administration in 1997 will not infringe U.S Patent 4,591,592." Pl.'s Teva I Mem. in Supp. at 4. Syntex preferred that the parties file a motion to dismiss based on the fact that they all agreed that Teva's product would not infringe

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not consider any party's argument of judicial estoppel here.

Syntex's patent and that the patent would not be enforceable against Teva. Id. Syntex then filed a motion to dismiss.

At the motions hearing, Teva argued that it had a reasonable apprehension of suit when it filed the declaratory judgment action, Dist. Ct. Tr. from Teva-Syntex Litig. at 9; Syntex argued that no reasonable apprehension of suit ever existed, Dist. Ct. Tr. from Teva-Syntex Litig. at 5-6. Syntex took the position that since Teva never experienced any threat of suit, Teva should not be entitled to a dismissal that expressly included a finding of non-infringement, because such a finding would be a "decision of a court . . . holding the patent . . . not infringed," and TorPharm's 180-day exclusivity clock would then be triggered. Dist. Ct. Tr. from Teva-Syntex Litig. at 6. This would give Teva an advantage by allowing it to bring its subordinate generic product to market more quickly. Id. The trial judge refused to make any findings with respect to whether Teva ever had a reasonable apprehension of suit, stating instead that

> . . . you are all leading me beyond the point of this motion, which is the fact that I have no jurisdiction . . . . [Y]ou all agree that that letter eliminates any controversy in this case. As of now there is, and as of the moment of filing . . . because of the crossing in the mails, there was no case of [sic] controversy. Well, there is no case of [sic] controversy under Article III. Now that's as far as I intend to go . . . . Once there is a decision here that there is no case or controversy, you're out the door. My file is taken away from me.

Dist. Ct. Tr. from Teva-Syntex Litig. at 23.

The final order of dismissal, entered on August 14, 1998, reads as follows:

> Based on all the evidence and argument, both written and oral, and good cause appearing therefor, the Court hereby finds:
> (1) Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") ~~lacked and~~ lacks a reasonable apprehension of suit by Syntex for infringement of U.S. Patent No. 4,591,592 ("'592 Patent").

> (2) There is no justiciable case or controversy between the parties concerning any infringement by Teva of the '592 Patent.
> (3) This Court lacks subject matter jurisdiction over the action.
> Based on the foregoing findings, Syntex's Motion is **GRANTED** and the Complaint is **DISMISSED**.

The order concluded with the phrase "**IT IS SO ORDERED**" above the signature of the district court. Dist. Ct. Dism. in Teva-Syntex Litig. When Syntex had submitted its motion to dismiss -- which the district court explicitly granted in the dismissal order -- Syntex had advised the court that, under Federal Rule of Civil Procedure 12(b)(1), the court was not limited to the pleadings but instead could consider materials other than the pleadings. Teva I, 182 F.3d at 1006.

FDA tentatively approved Teva's generic ticlopidine product on October 29, 1998, informing Teva that it could begin marketing generic ticlopidine following TorPharm's 180-day exclusivity period. See Pl.'s Teva I Mem. in Supp. at 4. FDA did not recognize the Teva-Syntex dismissal as a "decision of a court . . . holding the patent . . . not infringed" under the Hatch-Waxman Act; thus, TorPharm's 180-day clock had not yet been triggered. Id. Teva then filed an action in this Court against FDA, seeking injunctive relief that would require FDA to recognize TorPharm's 180-day exclusivity period as having begun on August 14, 1998 -- the date of the Teva-Syntex dismissal. Id. at 1-2. The district court denied this relief, based on three findings: (1) the Teva-Syntex dismissal was not contemplated by the plain language of the Hatch-Waxman Act; (2) assuming the language of the Hatch-Waxman Act was ambiguous, Teva was unlikely to prevail on the merits because it would not be able to show that FDA's interpretation was implausible; and (3) Teva had erroneously relied on case law from the Federal Circuit that did not directly address the Hatch-Waxman provision at issue. See Teva I, 182 F.3d at 1007.

Ultimately, the Court determined that only a decision on the merits could satisfy the Hatch-Waxman Act's "decision of a court" requirement. Id. Teva then appealed to the D.C. Circuit. See Teva I, 182 F.3d at 1004.

The D.C. Circuit reversed, finding that FDA's action was "arbitrary and capricious" and that the denial of injunctive relief constituted an abuse of discretion. See id. at 1007, 1012. The Teva I opinion notes that "[a] 'decision' can take several forms," id. at 1007-08, and makes clear that a judgment on the merits is not necessary, see id. at 1009. Rather, the court noted, "the significance of a court's 'decision' or 'holding' often lies in its preclusive effect." Id. at 1008. The court acknowledged that not every action taken by a court will constitute a "decision" or "holding," and drew a distinction between a typical dismissal for lack of subject matter jurisdiction and the Teva-Syntex dismissal: an ordinary dismissal for lack of subject matter jurisdiction is not preclusive "because the court lacked authority or competence to hear and decide the case," id., but the Teva-Syntex dismissal "was based exclusively and necessarily on Syntex's declaration that Teva's product would not infringe its patent and its express disavowal of an intent to sue," id. The court noted that Syntex had specifically asked the district court to consider more than just the pleadings, and that the court looked to both the June 8, 1998 letter and the declaration of non-infringement from Syntex's counsel when it reviewed Syntex's motion to dismiss. Id.

In short, the D.C. Circuit concluded that Syntex's motion, which included the three findings of fact that were physically incorporated into the final dismissal order, only came about because of Syntex's own admissions and promises, which had eradicated any case or controversy concerning a future patent enforcement action against Teva. Id. Specifically, the court stated

that

> [Syntex's] motion was granted on the basis of an express finding of fact by the California court regarding Teva's reasonable nonapprehension of suit, as Syntex itself had proposed as part of its motion to dismiss. From the perspective of the California court, then, Syntex's declaration and conduct eliminated the need for a declaratory judgment because Syntex would be estopped from challenging Teva's marketing of its generic drug on the ground of patent infringement.

Id.

Hence, the court in Teva I concluded that the district court made an implicit finding of fact when it approved and signed the Teva-Syntex dismissal, to the effect that the conduct of Syntex would prevent Syntex from ever suing Teva for infringement. As the court stated, "the California dismissal appears to meet the requirements of a triggering 'court decision' because that court had to make a *predicate finding* with respect to whether Syntex would ever sue Teva for infringement in order to conclude that there was no case or controversy between the parties." Id. at 1009 (emphasis added). If there is no need for a judgment on the merits because the trial judge has concluded that a dismissal will preclude a future suit for patent infringement, then that dismissal is a court decision holding the patent not infringed and will trigger the 180-day clock under the Hatch-Waxman Act. See id. at 1009. The key inquiry is whether the trial judge has made an implicit, predicate finding, for it is the process through which the trial judge makes such a finding that serves to qualify the dismissal under the statutory language. The Teva I court remanded the case for further consideration of the request for injunctive relief.

On remand, FDA continued to insist that the Teva-Syntex dismissal was not a "decision" within the meaning of Hatch-Waxman because the dismissal did not, within its four corners, state that the patent-in-suit was not infringed. Teva II, 2000 WL 1838303 at *2. FDA refused to look

at the June 8, 1998 letter, or the admissions of Syntex's counsel, because to do so would compromise its administrative convenience. Id. at *1-2; see also Teva Pharms., USA, Inc. v. FDA, Civ. No. 99-67, 1999 WL 1042743 at *5 (D.D.C. Aug. 19, 1999). This time, the district court found for Teva, holding that although the FDA's concerns about administrative convenience were both relevant and genuine, they were not implicated in light of the "unique circumstances" surrounding the Teva-Syntex dismissal. See Teva II, 2000 WL 1838303 at *1. FDA had committed to a case-by-case assessment, and FDA simply needed to look at the dismissal order and the June 8, 1998 letter because, "[a]s a matter of black-letter patent law, these documents suffice to forever estop [Syntex] from suing Teva for patent infringement." Id. (quoting Teva Pharms., USA, Inc., 1999 WL 1042743 at *5). FDA appealed the district court's decision to the D.C. Circuit.

On appeal, the D.C. Circuit affirmed, finding that FDA's determination that the 180-day clock was not triggered "fail[ed] for want of reasoned decisionmaking." Teva II, 2000 WL 1838303 at *2. Because FDA had previously obligated itself to undertake a case-by-case inquiry in making such a determination, its actions here were arbitrary and capricious -- by refusing to mold its analysis to the specifics of the case, namely the incorporation of the June 8, 1998 letter into the Teva-Syntex dismissal and the context of that dismissal, FDA had not in fact engaged in a case-by-case inquiry. Id. Teva II did not develop in a vacuum, and it is not entirely severable from Teva I. The lesson of Teva II, then, is that when a dismissal includes a predicate finding of fact by the trial judge, which is based on documents other than the pleadings that have functionally become part of the dismissal order, and FDA has committed itself to a case-by-case analysis of such dismissals, FDA's determination as to whether the dismissal is a "decision of a

court" under the language of Hatch-Waxman will not stand unless the agency has considered all of the materials that constitute the dismissal order. Put another way, Teva II does not mandate that a reviewing entity always look beyond the four corners of a dismissal order; rather, it mandates that when, under the particular circumstances of a case, those four corners have been expanded to include other papers, they must also be considered.

2. The Instant Case

The initial inquiry must be whether the BMS-Apotex dismissal constitutes a "decision" or "holding" under § 355(j)(5)(3)(iv)(II). If it does not, then the statutory trigger requiring a "decision of a court" is not satisfied, and Teva's 180-day exclusivity period has neither expired nor even commenced. The issue requires an assessment of whether the terms of the parties' private agreement must be considered part of the dismissal order or whether, instead, the district court was divested of jurisdiction when the parties filed the executed stipulation. If the latter, then the district court necessarily lacked the ability to create a "decision" or "holding" when it signed and entered the dismissal order. Teva submits that Second Circuit law controls on this issue; FDA contends that D.C. Circuit law controls. To be sure, there is some logic that suggests Second Circuit law would be most appropriate -- the BMS-Apotex litigation was filed in the Southern District of New York, a judge of that court reviewed and signed the stipulation, and the dismissal was entered there as well. But the Court is also mindful of the practical difficulties that might plague FDA if it were required to assess the law of different jurisdictions whenever presented with a "decision of a court" inquiry. In any event, the Court is confident that the outcome here is the same under the law of either jurisdiction.

The general rule in the Second Circuit is that if a plaintiff files a stipulation of dismissal,

and this stipulation contains the signature of all parties and is mutually consensual, then Federal Rule of Civil Procedure 41(a)(1)(ii) automatically "divests the court of its jurisdiction over the case, irrespective of whether the district court approves the stipulation." Gambale v. Deutsche Bank AG, 377 F.3d 133, 139 (2d Cir. 2004); see Hester Indus., Inc. v. Tyson Foods, Inc., 160 F.3d 911, 916 (2d Cir. 1998). Stipulated dismissals reflecting settlements -- and matters relating to their enforcement -- are consistently interpreted in accordance with the law of contracts. See Geller v. Branic Int'l Realty Corp., 212 F.3d 734, 737 (2d Cir. 2000); see also Solv-Ex Corp. v. Quillen, 1999 WL 311808 at *2 (S.D.N.Y. 1999) (unpublished disposition) (stating that Rule 41(a)(1)(ii) dismissals are "in the nature of a contractual agreement among the parties"). As such, elementary principles of contract construction apply, which require that the stipulation be interpreted according to its plain language. Cf. Williamsburg Fair Housing Comm. v. New York City Housing Auth., 450 F. Supp. 602, 608 (S.D.N.Y. 1978) (stating that "'consent decrees . . . are to be read within their four corners, and . . . are binding only to the extent to which they go'" (quoting Dart Drug Corp., 320 F.2d at 749)). But cf. Solv-Ex Corp., 1999 WL 311808 at *2 (unpublished disposition) (looking beyond the plain language of the stipulation to a transcript from a hearing, which the stipulation incorporated by reference).

The seminal Second Circuit case is Hester Indus., Inc. v. Tyson Foods, Inc., 160 F.3d 911 (2d Cir. 1998). Hester involved a contempt order that the trial judge entered against one of the parties, after the case had been dismissed by stipulation, for violating the underlying settlement agreement. See Hester, 160 F.3d at 912-14. The stipulated dismissal contained the trial judge's signature and stated that the case was dismissed with prejudice "pursuant to rule 41 of the Federal Rules of Civil Procedure and in accordance with the terms of the attached Settlement

Agreement between the parties." Id. at 913. Based on this language, the district court found that its dismissal order incorporated the settlement agreement; thus, a breach of that agreement could support a finding of contempt. Id. at 914. Specifically, the court stated that "the wording of the [dismissal] order logically leads one to find that the terms of the settlement agreement were conditions approved by the [c]ourt through the dismissal order and, thus, were incorporated into the order." Id. The Second Circuit reversed, finding that because the dismissal was effectuated by mutual agreement of the parties, no judicial action was required, and the judge's signature on the dismissal did not function to change the nature of the dismissal. See id. at 916. The district court lacked authority to condition dismissal on the parties' compliance with the agreement precisely for this reason. Id.; cf. Steiner v. Atochem, S.A., 2002 WL 1870322 at *4 (S.D.N.Y. 2002) (unpublished disposition) (stating that "the court in effect never exercised jurisdiction with respect to entry of the voluntary dismissal because it was effective automatically without court approval" (citing Hester, 160 F.3d at 916)).

In order for underlying terms of settlement to become enforceable as part of the dismissal order, a two-part test must be satisfied: (1) the terms of the underlying agreement must be physically included in the dismissal order itself, and (2) there must be "some evidence that a district court intended to place its 'judicial imprimatur' on the settlement [terms]." Torres v. Walker, 356 F.3d 238, 245 n.6 (2d Cir. 2004).[5] The Torres court concluded that because the stipulation before it lacked a provision expressly permitting the district court to retain jurisdiction

[5]The Second Circuit recently described this portion of Torres as "footnoted dictum" before going on to state that, even if these requirements of Torres applied to the case before it, they were satisfied. A.R. v. Bd. of Educ. of N.Y., 407 F.3d 65, 78 n.14 (2d Cir. 2005).

to monitor compliance with the terms of the parties' settlement, the terms of the agreement were not judicially enforceable. Id. at 244-45. Without record evidence confirming that the trial court "carefully reviewed the terms of the stipulation . . . or . . . reviewed it at all before 'so ordering' it," id. at 245, and without anything in the stipulation that obligated the court to perform functions that the parties themselves lacked the power to perform, id; see also Geller, 212 F.3d at 737, the stipulation was merely a "private settlement agreement" that lacked the requisite judicial imprimatur, see Torres, 356 F.3d at 245.

The analysis in Torres included a lengthy deconstruction of two Supreme Court cases: Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375 (1994), and Buckhannon Bd. & Care Home v. W. Va. Dep't of Health & Human Res., 532 U.S. 598 (2001). Kokkonen held that there is no ancillary jurisdiction to enable a federal trial court to issue an order that enforces a private settlement agreement. See Kokkonen, 532 U.S. at 380. The Court hypothesized that a different conclusion could be supported if the parties were obligated, by the terms of the dismissal order, to comply with the terms of the settlement agreement. Id. at 381. There are two ways to accomplish this: (1) through a provision in the dismissal order that expressly preserves the court's jurisdiction over the settlement agreement, or (2) through physical incorporation of the terms of the settlement agreement into the dismissal order. Id. Buckhannon pronounced that private settlements are not the equivalent of consent decrees because they require a lesser degree of judicial involvement. See Buckhannon, 532 U.S. at 604 n.7. In the Second Circuit, if a district court expressly retains jurisdiction over the enforcement of the parties' settlement agreement, then there is an adequate "judicial imprimatur" under Kokkonen and Buckhannon, because the degree of judicial involvement is substantially similar to that associated with a

consent decree. Roberson v. Giuliani, 346 F.3d 75, 82 (2d Cir. 2003).

Based on this authority, the Court concludes that the BMS-Apotex dismissal order lacks the necessary judicial imprimatur to convert the parties' private agreement underlying the stipulation into an enforceable provision of the dismissal order. Although the dismissal order recites that it is based upon BMS's pre-suit representations, it neither explicitly retains jurisdiction over the enforcement of those representations nor physically incorporates them. For this reason, and consistent with Rule 41(a)(1), court action was not required, and the presence of the district court's signature on the dismissal order has no effect on the character of the dismissal under Hester. Indeed, the Supreme Court has proclaimed that a "judge's mere awareness and approval of the terms of the settlement agreement do not suffice to make them part of [the] order." Kokkonen, 511 U.S. at 381. The BMS-Apotex stipulation, then, remains a private settlement agreement, not a consent decree or the functional equivalent thereof, under Second Circuit law. See Torres, 356 F.3d at 245; Roberson, 346 F.3d at 82. Thus, there is no predicate finding by the district court because it could not "hold" anything once the parties had signed and filed the stipulation of dismissal. Any commitment or determination that BMS could not sue Apotex in the future was made by the parties alone, not by the district court.

The conclusion is no different under the somewhat less-developed authority in the D.C. Circuit, as might be expected in light of the fact that the Second Circuit's approach is built upon Supreme Court precedent. The D.C. Circuit recognizes that a dismissal without prejudice under Rule 41(a)(1)(ii) "is effective immediately and does not require judicial approval." In re Wolf, 842 F. 2d 464, 466 (D.C. Cir. 1988); cf. Oil, Chemical and Atomic Workers Int'l Union v. Dep't of Energy, 288 F.3d 452, 458 (D.C. Cir. 2002) (stating that a voluntary dismissal that is signed by

all parties and effectuated without court action under Rule 41(a)(1) does not constitute "judicial relief" under Buckhannon). This Circuit has a legacy of strictly construing consent decrees because "they represent the agreement of the parties, and not the independent examination of the subject-matter by the court." Dart Drug Corp., 320 F.2d at 749. Such agreements are "'read within their four corners,'" and "'[n]either court nor party can write in them what is not there, and thus change what was agreed upon by the parties.'" Id. (quoting Star Bedding Co. v. Englander Co., 239 F.2d 537, 542 (8th Cir. 1957)); Jane Does I Through III v. District of Columbia, 238 F. Supp. 2d 212, 218 (D.D.C. 2002) (citing Dart Drug Corp., 320 F.2d at 749). As in the Second Circuit, Kokkonen is interpreted to require that a party who wishes a court to retain jurisdiction over its settlement agreement must request the court to do so on the face of the dismissal. See Shaffer v. Veneman, 325 F.3d 370, 473-74 (D.C. Cir. 2002). Absent some remaining basis for jurisdiction over the underlying suit, a district court cannot enforce the settlement agreement. See Mutual of Omaha Ins. Co. v. Nat'l Ass'n of Gov't Employees, Inc., 145 F.3d 389, 394 (D.C. Cir. 1998).

This Court therefore concludes that, under both Second Circuit and D.C. Circuit law, the BMS-Apotex dismissal is not a "decision of a court" under the Hatch-Waxman Act and, accordingly, the 180-day exclusivity period for Teva as the first ANDA applicant was not triggered by the filing or court approval of that dismissal.

Teva I and Teva II are consistent with this outcome. The BMS-Apotex dismissal in the Southern District of New York (at issue in the instant case) is, in several ways, distinguishable from the Teva-Syntex dismissal in the Central District of California (at issue in the previous Teva litigation). To begin with, the latter resulted directly from a motion to dismiss, not a

consensual stipulation procured and filed under Rule 41(a)(1)(ii). The Teva-Syntex dismissal also physically incorporated the terms of Syntex's proposed dismissal into the four corners of the court order, and Syntex expressly sought to have the district court consider more than just the pleadings. The Teva-Syntex dismissal expressly stated, on its face, that the court found "good cause" for the dismissal, and that this good cause was "based on all the evidence and argument, both written and oral." Dist. Ct. Dism. in Teva-Syntex Litig. Moreover, the Teva-Syntex dismissal was not wholly uncontested -- indeed, there was a hearing on the motion regarding the terms, if any, to be attached to the dismissal, and the parties argued passionately at that hearing. The D.C. Circuit found, in Teva I, that the district court had made a predicate finding of fact when it dismissed the Teva-Syntex litigation. That finding is also evidenced by the transcript from the dismissal hearing, in which the district court verbally concluded that "[a]s of now there is, and as of the moment of filing . . . because of the crossing in the mails, there was no case or controversy. . . . [T]here is no case of [sic] controversy under Article III." Dist. Ct. Tr. from Teva-Syntex Litig. at 23.

The same cannot be said with respect to the BMS-Apotex dismissal at issue here. This dismissal was wholly voluntary and entirely uncontested. The party that filed the suit (Apotex) voluntarily procured a consensual stipulation of dismissal under Rule 41(a)(1)(ii), which was based on pre-suit representations. The underlying terms of the stipulation are not physically incorporated into the four corners of the dismissal order, and there is no statement of a "good cause" finding on the face of the order. Neither Apotex nor BMS ever asked the district court to look beyond the signed stipulation, and no hearing or argument ever took place. Thus, the district court could only review the voluntary, private settlement agreement: it did not have to

weigh evidence, or make any implicit determinations. Indeed, it did not even have to sign the document, and under Second Circuit and D.C. Circuit law, as well as Rule 41(a)(1)(ii), the filing of the signed stipulation of dismissal automatically effectuated the dismissal without any court action. The district court was divested of jurisdiction at the very moment that the stipulation, containing the signatures of both BMS and Apotex, was filed -- there cannot have subsequently been any predicate finding of fact as to estoppel or any other issue. And there is nothing in the record to suggest that, notwithstanding this jurisdictional bar, any predicate finding of fact was actually made.

Hence, for the reasons explained, the BMS-Apotex dismissal at issue here is not a court decision or holding under Second Circuit or D.C. Circuit precedent. Under the law of both jurisdictions, that dismissal lacks sufficient judicial imprimatur to transform it from a private agreement between the parties into a finding of fact made by the district court. In contrast, when that same body of law is applied to the Teva-Syntex dismissal at issue in Teva I and Teva II, it is plain that the dismissal does meet the requirements for a court decision. The district court in the Teva-Syntex litigation made an implicit, predicate finding of fact that, because of the statements Syntex made to Teva, Syntex was estopped from suing Teva for infringement. No such finding of fact was made by the district court in the BMS-Apotex litigation that underlies the instant case, because that court no longer had the power to make any judicial findings once the consensual stipulation of dismissal, containing the signatures of both parties, was filed. The signature of the district court in the BMS-Apotex litigation was legally superfluous. For this reason, the BMS-Apotex dismissal and the Teva-Syntex dismissal fall neatly within the lines of distinction drawn by the D.C. Circuit in Teva I: the former constitutes the ordinary dismissal for

lack of subject matter jurisdiction, which is non-preclusive "because the court lacked authority or competence to hear and decide the case." Teva I, 182 F.3d at 1008. The latter, however, embodies the exceptional circumstance in which a dismissal for lack of subject matter jurisdiction is preclusive, because the district court in that case made an actual, predicate finding of fact in the context of a contested motion. See id.

Accordingly, the BMS-Apotex dismissal is not akin to the Teva-Syntex dismissal, and it does not constitute a "decision of a court" or "holding" under governing law. It therefore satisfies neither the plain language of the Hatch-Waxman Act nor the dictates of the previous Teva cases.[6] Thus, Teva's 180-day exclusivity clock was never triggered, and the Court concludes that FDA's determination to the contrary was "arbitrary, capricious . . . or otherwise not in accordance with the law" under § 706(2) of the APA.

CONCLUSION

For the reasons expressed herein, Teva's motion for injunctive relief will be granted. A

[6]The Court's analysis need not go any further. The Court does note, however, that the preclusion issue has been a major part of this litigation. In the BMS-Apotex litigation that underlies this case, Apotex never had a reasonable apprehension of suit -- that is, there was never any case or controversy between the parties, because BMS repeatedly assured Apotex that it would not sue for infringement. Under the law of the Federal Circuit, which controls on the issue of patent estoppel, there is a distinction between the type of assurances that are sufficient to prevent a reasonable apprehension of suit from arising in the first place, and those that are required to eradicate an already-existing reasonable apprehension. Compare Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361 (Fed. Cir. 2004), and Fina Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1482-84 (Fed. Cir. 1998), and Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054 (Fed. Cir. 1995), and C.R. Bard, Inc. v. Schwartz, 716 F.2d 874 (Fed. Cir. 1983), with Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631 (Fed. Cir. 1991). A broad, formal covenant not to sue is required in order to eradicate a preexisting apprehension, whereas something less -- a mere disavowal of intent to sue -- will prevent the apprehension from arising at all. See Fina Research, 141 F.3d at 1484. The representations made by BMS in this case sufficed to prevent any reasonable apprehension from arising; therefore, they also preclude BMS from suing Apotex for infringement. This case thus embodies the peculiar circumstance in which the words of BMS are preclusive, but they are not part of a "decision" or "holding" within the meaning of the Hatch-Waxman Act.

separate order will be posted on this date.

/s/ John D. Bates
JOHN D. BATES
United States District Judge

Dated: October 21, 2005

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